

REMARKS

Claims 10, 13-16, 22-26, 36-38 and 41-42, as amended, and new claims 45-53 appear in this application for the Examiner's review and consideration. Claims 19-21, 39-40 and 43-44 are cancelled. Claims 10 and 36 have been amended to further distinguish the present invention from the prior art. Claims 16, 22 and 23 have been amended to recite the specific treatments of "thermal or chemical burns", which has been indicated by Examiner as being enabled by the disclosure. Claim 26 has been amended for clarity. Claims 41 and 42 have been amended to fulfill the enablement requirement. New claims 45-53 recite the deleted features of the original claim 16 and its dependent claims. As no new matter is added, entry of the amendments at this time is respectfully requested.

In preparing this response, it was found that the sixth amino acid in SEQ ID NO:16 of the CRF, which should be Glu, was replaced by Asp by mistake. A substitute sequence listing with the corrected sequence, which fully complies with the sequence listing requirements, is submitted concurrently with this amendment.

Claims 16, 19-26 and 39-44 are rejected under 35 U.S.C. 112, first paragraph, the enablement requirement. Claims 16, 22 and 23, as amended, and dependent claims 24-26, are directed to the use of the pharmaceutical compositions comprising peptides of SEQ ID NOS: 1, 2, 4-8, 10-14 and 16 to thermal or chemical induced burns, which has been indicated by the Examiner as enabled by the disclosure. Thus, rejections of claims 16 and 22-26 should be withdrawn.

Applicant wishes to point out that Applicant has demonstrated the anti-inflammatory effect of the "3m1" peptide (having SEQ ID NO:13) in carrageenan-induced inflammation in the International Publication No. WO 2005/090387 (see Examples 16 and 17 of WO 2005/090387). Furthermore, U.S. Patent Application No. 11/527,162 (hereafter "the '162 application"), a Continuation-In-Part application of the current application, discloses the anti-inflammatory effect of the peptide of SEQ ID NO:13 on peritonitis, glucose-induced edema, and sepsis in mice (see Examples 27-28 and 30 of the '162 application). These examples demonstrate that there is sufficient disclosure to enable a skilled artisan to use the compositions comprising SEQ ID NOS: 1, 5-8, 10-14 and 16 to treat inflammatory diseases. Thus, the new claims 45-53, reciting the use of a

pharmaceutical composition comprising peptides of SEQ ID NOs: 1, 5-8, 10-14 and 16 in treating inflammatory diseases, are enabled.

In addition, the '162 application further discloses the effect of the peptide of SEQ ID NO:13 on Parkinson's disease in mice (see Example 29 of the '162 application). Thus, the amended claims 41 and 42, which recite the use of a composition comprising a peptide of SEQ ID NOs: 1, 5-8, 10-14 and 16 in treating Parkinson's disease, are enabled and rejections of claims 41 and 42 should be withdrawn.

In view of the forgoing and the cancellation of the claims 39-40 and 43-44, all rejections under 35 U.S.C. 112, first paragraph, the enablement requirement, have been overcome and should be withdrawn.

Claims 10, 16, 19, 22, 24-26 and 36 are rejected under 35 U.S.C. 102(a) as being anticipated by Masuda & Sugiyama (*Peptides* 22:1511 (2001)). Claims 10, 16, 19-22, 24-26, 36, 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Scherer et al. (*Clin. Exp. Immunol.* 40:49 (1980)). Claims 10, 16, 19-22, 24-26, 36, 41, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,468,537 to Datta et al. Claims 10, 16, 20-22, 24-26, 36, 43 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Publication No. US 2004/0039157 to Staton et al. In response, Applicant has deleted the phrase "analog, homologs or derivatives" in claims 10 and 36, as suggested by the Examiner as sufficient to overcome these rejections, and added the phrase "N-methylated analogs", which is supported by the disclosure in paragraph [0052] of the published application, for clarity. Thus, all anticipation rejections have been overcome and should be withdrawn.

Claims 10, 16, 21 and 36 are provisionally rejected on the ground of obviousness-type double patenting over certain claims of co-pending application No. 11/527,162. Applicant submits that since the provision has not occurred, this rejection should be withdrawn at this time. Should the cited co-pending application be allowed prior to this one, Applicant will submit the necessary terminal disclaimer or appropriate arguments to overcome these rejections.

Applicant respectfully points out that the Examiner's comment # 15, "In the response filed 8/30/2006, Applicant has presented data suggesting that SEQ ID NO:9 is

pro-angiogenic...", is incorrect. Applicant has stated explicitly that SEQ ID NO:9 and other related peptides are anti-angiogenic on page 13 of the Amendment filed on August 30, 2006 :"In contrast, human Fibrinopeptide A, a 15-mer peptide having the amino acid sequence ADSGEGDFLAEGGGV of **SEQ ID NO:9**, and guinea pig Fibrinopeptide A peptide or analogs thereof of SEQ ID NOs:2, 3, and 4, consisting of 12 to 14 amino acid residues each, have been surprisingly found by Applicant to be useful for **preventing or treating malignant or benign tumors.**"(emphasis added).

In view of the above, the entire application is believed to be in condition for allowance, early notification of such would be appreciated. Should the Examiner not agree, a personal or telephonic interview is respectfully requested to discuss any remaining issues in order to expedite the eventual allowance of the claims.

Respectfully submitted,

Date

1/9/07



Allan A. Fanucci
(Reg. No. 30,256)

WINSTON & STRAWN LLP
CUSTOMER NO. 28765
(212) 294-3311